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Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Randall et al.

Art Unit 1638

U.S. Patent No. 6,773,917

Issued August 10, 2004

Application Serial No. 09/685,296

Filed October 10, 2000

Confirmation No. 4557

For USE OF DNA ENCODING PLASTID PYRUVATE DEHYDROGENASE AND  
BRANCHED CHAIN OXOACID DEHYDROGENASE COMPONENTS TO ENHANCE  
POLYHYDROXYALKANOATE BIOSYNTHESIS IN PLANTS

Examiner: Russell Kallis

August 10, 2004

**REQUEST FOR RECONSIDERATION OF THE PATENT TERM ADJUSTMENT**  
**PURSUANT TO 37 CFR 1.705**

TO THE COMMISSIONER OF PATENTS,  
SIR:

In response to the Issue Notification dated July 22, 2004, in the above-referenced patent application, applicants respectfully request reconsideration of the patent term adjustment determination. Pursuant to 37 CFR § 1.705(b) and/or (d), applicants submit the following statement of facts in support of this request for reconsideration.

The application was filed on October 10, 2000. The first Office action (restriction requirement) was mailed on April 22, 2002, which is one-hundred thirty-three (133) days after the fourteen (14) month due date for the mailing of a first office action on the merits. The response to the first Office action was filed on June 24, 2002, which is within the three (3) month shortened statutory period for response. The second Office action was mailed on August 29, 2002, which is within the four (4) month period for reply by the Office. The response to the second Office action was filed on February 6, 2003, which is

sixty-nine (69) days after the three (3) month shortened statutory period for response. The third Office action (a final Office action) was mailed on May 20, 2003, which is within the four (4) month period for reply by the Office. Following a telephone interview on September 9, 2003, involving Examiner Russell Kallis, attorney Edward Hejlek, and the undersigned attorney, a response to the third (final) Office action was filed on September 11, 2003, which is 22 days after the three (3) month shortened statutory period for response. The Notice of Allowance was mailed October 2, 2003, which is within the four (4) month period for reply by the Office, and indicated that the subject application was entitled to a patent term adjustment of sixty-four (64) days. The Issue Fee was paid on December 18, 2003, which is within the three (3) month period for payment of an Issue Fee, along with a letter pursuant to Comment 43 of the rules listed in Federal Register Vol. 65, No. 181 at page 56387 (Sept. 18, 2000) ("Comment 43 letter"), indicating that applicants believed themselves to be entitled to only 42 days of patent term extension. The Issue Notification was mailed July 22, 2004, indicating that the patent would issue on August 10, 2004, which is one-hundred fourteen (114) days after the four (4) month period for issuance of a patent subsequent to the payment of an issue fee and fifty-eight (58) days after the three (3) year period for issuance of a patent (less the already credited Office delay). The Issue Notification further indicated that the subject application is entitled to a patent term adjustment of one-hundred sixteen (116) days.

Based upon the above-recited facts, the delay on the part of the Office was 305 days. The delay on the part of applicants was 91 days. The result is a patent term extension of 214 days, or

98 days greater than the patent term adjustment indicated in the Issue Notification.

Based upon a review of the Patent Application Information Retrieval (PAIR) database regarding the subject application, it appears that the Office inadvertently failed to record applicants' September 11, 2003, response to the third (final) \* office action.<sup>1</sup> Instead, the next response of applicants' recorded by the Office after the mailing of the third (final) Office action was applicants' Comment 43 letter filed in response to the Notice of Allowance. Accordingly, instead of citing applicants for a twenty-two (22) day delay (*i.e.*, the delay resulting from applicants filing a response to the third Office action twenty-two (22) days after the three (3) month shortened statutory period for response), applicants were incorrectly cited with a one-hundred twenty (120) day delay (this number being the number of days between the end of the three (3) month shortened statutory period for response to the third Office action and the filing of the Comment 43 letter). Accordingly, by inadvertently failing to record applicants' September 11, 2003, response to the third (final) Office action, the Office mistakenly failed to credit the applicant with an additional 98 days of patent term adjustment.

Moreover, the filing of applicants' Comment 43 letter is not considered the filing of an "other paper" submitted after a Notice of Allowance under 37 CFR § 1.704(c)(10). Section 1.704(c)(10) is designed to penalize applicants who submit papers

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<sup>1</sup> Copies of (1) the September 11, 2003, response, (2) the Express Mail Label from the envelope containing the response, and (3) the return postcard that accompanied the response and that is stamped as received by the Office of Initial Patent Examination (OIPE) are enclosed herewith.

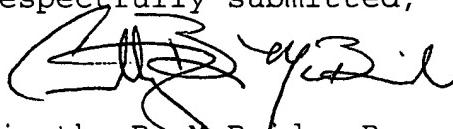
after the Notice of Allowance that constitute a failure to engage in reasonable efforts to conclude prosecution under the general principles of 35 U.S.C. § 154(b)(2)(C)(i). Section 1.704(c)(10) is clearly **not** designed to penalize applicants who file responses that are required as a result of information first made known to applicants by the Office in the Notice of Allowance.

Accordingly, applicants believe that the patent term adjustment should be increased by 98 days (representing the period of September 11, 2003, to December 18, 2003). This correction should bring the total patent term adjustment to 214 days. Applicants respectfully request a correction in the patent term adjustment to reflect the same.

A terminal disclaimer was not filed in this case.

\* A check in the amount of \$200.00 is enclosed to pay for the fee under 37 CFR § 1.18(e). Please charge any under payment or credit any overpayment to deposit account No. 19-1345.

Respectfully submitted,



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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Randall et al.

Art Unit 1638

Serial No. 09/685,296

Filed October 10, 2000

Confirmation No. 4557

For USE OF DNA ENCODING PLASTID PYRUVATE DEHYDROGENASE AND  
BRANCHED CHAIN OXOACID DEHYDROGENASE COMPONENTS TO ENHANCE  
POLYHYDROXYALKANOATE BIOSYNTHESIS IN PLANTS

Examiner R. Kallis

September 11, 2003

AMENDMENT C - RESPONSE TO FINAL OFFICE ACTION

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS

Sir:

In response to the final Office action mailed May 20, 2003,  
please enter the following amendments.**Amendments to the Claims** are reflected in the listing of claims  
which begins on page 2 of this paper.**Remarks/Arguments** begin on page 8 of this paper.

AMENDMENTS

This listing of claims will replace all prior versions and listings of claims in the prior application:

Claim 45. (currently amended) A transformed plant, a plastid of which comprises:

- (a) a polypeptide encoded by a nucleotide sequence encoding a branched chain oxoacid dehydrogenase complex E1 $\alpha$  subunit protein, said nucleotide sequence selected from the group consisting of:
  - (i) the nucleotide sequence shown in SEQ ID NO:11, or the complement thereof;
  - (ii) a nucleotide sequence that hybridizes to said nucleotide sequence of (i) under a wash stringency equivalent to 0.1X SSC ~~to 2.0X sse~~, 0.1% SDS, at ~~55-~~ 65°e 55°c, and which encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E1 $\alpha$  subunit by about 30% or less;
  - (iii) a nucleotide sequence encoding the same amino acid sequence as said nucleotide sequence of (i), but which is degenerate in accordance with the degeneracy of the genetic code; and
  - (iv) a nucleotide sequence encoding the same amino acid sequence as said nucleotide sequence of (ii), but which is degenerate in accordance with the degeneracy of the genetic code;
- (b) a polypeptide encoded by a nucleotide sequence encoding a branched chain oxoacid dehydrogenase complex E1 $\beta$  subunit protein, said nucleotide sequence selected from the group consisting of:

- (i) the nucleotide sequence shown in SEQ ID NO:13, or the complement thereof;
  - (ii) a nucleotide sequence that hybridizes to said nucleotide sequence of (i) under a wash stringency equivalent to 0.1X SSC ~~to 2.0X sse~~, 0.1% SDS, at ~~55-~~ ~~65°C~~ 55°C, and which encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E1 $\beta$  subunit by about 30% or less;
  - (iii) a nucleotide sequence encoding the same amino acid sequence as said nucleotide sequence of (i), but which is degenerate in accordance with the degeneracy of the genetic code; and
  - (iv) a nucleotide sequence encoding the same amino acid sequence as said nucleotide sequence of (ii), but which is degenerate in accordance with the degeneracy of the genetic code;
- (c) a polypeptide encoded by a nucleotide sequence encoding a branched chain oxoacid dehydrogenase complex E2 component protein, said nucleotide sequence selected from the group consisting of:
- (i) the nucleotide sequence shown in SEQ ID NO:15, or the complement thereof;
  - (ii) a nucleotide sequence that hybridizes to said nucleotide sequence of (i) under a wash stringency equivalent to 0.1X SSC ~~to 2.0X sse~~, 0.1% SDS, at ~~55-~~ ~~65°C~~ 55°C, and which encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E2 subunit by about 30% or less;

- (iii) a nucleotide sequence encoding the same amino acid sequence as said nucleotide sequence of (i), but which is degenerate in accordance with the degeneracy of the genetic code; and
  - (iv) a nucleotide sequence encoding the same amino acid sequence as said nucleotide sequence of (ii), but which is degenerate in accordance with the degeneracy of the genetic code; and
- (d) ~~a polypeptide encoded by a nucleotide sequence encoding an enzyme that enhances the biosynthesis of 2-oxobutyrate~~ an enzyme selected from the group consisting of aspartate kinase, homoserine dehydrogenase, threonine synthase, and threonine deaminase.

Claim 46. (previously presented) The plant of claim 45, wherein:

- (a) the nucleotide sequence in (a)(ii) encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E1 $\alpha$  subunit by about 20% or less;
- (b) the nucleotide sequence in (b)(ii) encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E1 $\beta$  subunit by about 20% or less; and
- (c) the nucleotide sequence in (c)(ii) encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E2 component by about 20% or less.

Claim 47. (previously presented) The plant of claim 45,  
wherein:

- (a) the nucleotide sequence in (a)(ii) encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E1 $\alpha$  subunit by about 10% or less;
- (b) the nucleotide sequence in (b)(ii) encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E1 $\beta$  subunit by about 10% or less;  
and
- (c) the nucleotide sequence in (c)(ii) encodes a polypeptide having enzymatic activity differing from that of *Arabidopsis thaliana* branched chain 2-oxoacid dehydrogenase complex E2 component by about 10% or less.

Claims 48-51. Canceled.

Claim 52. (currently amended) The plant of claim 45, wherein

- (a) the nucleotide sequence encoding a branched chain oxoacid dehydrogenase complex E1 $\alpha$  subunit protein is SEQ ID NO: 11;
- (b) the nucleotide sequence encoding a branched chain oxoacid dehydrogenase complex E1 $\beta$  subunit protein is SEQ ID NO: 13; and
- (c) the nucleotide sequence encoding a branched chain oxoacid dehydrogenase complex E2 component protein, is SEQ ID NO: 15, , and
- (d) ~~the nucleotide sequence encoding an enzyme that enhances the biosynthesis of 2-oxobutyrate is selected from the group of nucleotide sequences consisting of those that~~

~~encode aspartate kinase, homoserine dehydrogenase,  
threonine synthase, and threonine deaminase.~~

Claim 53. (previously presented) The plant of claim 52, wherein the enzyme that enhances the biosynthesis of 2-oxobutyrate is aspartate kinase.

Claim 54. (previously presented) The plant of claim 52, wherein the enzyme that enhances the biosynthesis of 2-oxobutyrate is homoserine dehydrogenase.

Claim 55. (previously presented) The plant of claim 52, wherein the enzyme that enhances the biosynthesis of 2-oxobutyrate is threonine synthase.

Claim 56. (previously presented) The plant of claim 52, wherein the enzyme that enhances the biosynthesis of 2-oxobutyrate is threonine deaminase.

Claim 57. (previously presented) The plant of claim 45, wherein the plant is a monocot.

Claim 58. (previously presented) The plant of claim 52, wherein the plant is a monocot.

Claim 59. (previously presented) The plant of claim 45, wherein the plant is a dicot.

Claim 60. (previously presented) The plant of claim 52, wherein the plant is a dicot.

Claim 61. (previously presented) The plant of claim 45,  
wherein the plastid is a seed plastid.

Claim 62. (previously presented) The plant of claim 52,  
wherein the plastid is a seed plastid.

Claim 63. (previously presented) The plastid of claim 61,  
wherein the seed plastid is a leucoplast.

Claim 64. (previously presented) The plastid of claim 62,  
wherein the seed plastid is a leucoplast.

Claim 65. (previously presented) The plant of claim 45,  
wherein the plastid is a leaf chloroplast.

Claim 66. (previously presented) The plant of claim 52,  
wherein the plastid is a leaf chloroplast.

Claim 67. (previously presented) The plant of claim 45,  
wherein the plant is *Arabidopsis*.

Claim 68. (previously presented) The plant of claim 52,  
wherein the plant is *Arabidopsis*.

REMARKS

With this response, claims 45-47 and 52-68 are pending. Claim 45 and 52 have been amended. Claims 48-51 have been canceled. Support for the amendments to claim 45 can be found in canceled claim 49, in claim 52 as previously presented, in the specification at p. 21, lines 14-29, and in the specification at p. 60, lines 17-20.

Applicants and the undersigned counsel acknowledge and thank Examiner Kallis for the courtesy extended during the September 4, 2003, interview. During this interview, the claim amendments presented herein, as well as the arguments regarding enablement and written description presented in Amendment B dated February 6, 2003, were discussed.

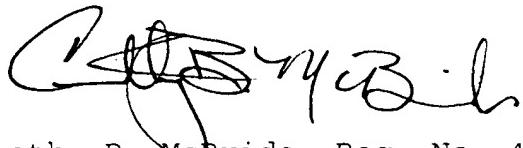
Agreement was reached as to the patentability of the amended claims presented herein. Specifically, recitation of the hybridization conditions in (a)(ii), (b)(ii), and (c)(ii) and of the enzymes in (d) of claim 45 were considered by the Office to have overcome the 35 U.S.C. 112, first paragraph written description rejection cited in the final Office action and to have placed claim 45 and all claims dependent therefrom in a condition for allowance. Moreover, it is Applicants' understanding that the arguments recited in Amendment B dated February 6, 2003, regarding enablement are considered by the Examiner to have overcome the 35 U.S.C. 112 first paragraph enablement rejection cited in the final Office action.

CONCLUSION

In light of the above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph, for lack of written description and under 35 U.S.C. 112, first paragraph, for lack of enablement.

Applicants request an extension of time to and including September 11, 2003, for filing a response to the above-mentioned final Office action. A check in the amount of the applicable extension fee is enclosed. The Commissioner is hereby authorized to charge any deficiency or overpayment in connection with this amendment to Deposit Account No. 19-1345.

Respectfully submitted,



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